

REMARKS

In response to the Office Action mailed May 31, 2007, favorable reconsideration is respectfully requested in view of the above amendments and the following remarks. Applicants have amended claim 19, support for which may be found throughout the specification as originally filed. No new matter has been added. The above amendments are not to be construed as acquiescence to the Examiner's stated grounds for rejections and are made without prejudice to prosecution of any subject matter removed or modified by this amendment in a related divisional, continuation or continuation-in-part application. Following the amendments, claims 19-26 remain pending and under examination in the application.

Rejections under 35 U.S.C. §112, First Paragraph (Written Description)

Claims 19-25 stand rejected under 35 U.S.C. §112, first paragraph, as allegedly containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the art that the inventors, at the time the application was filed, had possession of the claimed invention. The Examiner acknowledges that the instant specification provides adequate written description support for a method of stimulating an immune response using an isolated polypeptide comprising SEQ ID NO: 140. However, the Examiner alleges that there is insufficient written description to establish that Applicants were in possession of immunogenic portions of SEQ ID NO: 140 and sequences having at least 95% identity to SEQ ID NO: 140.

Applicants respectfully traverse this rejection and submit that the instant specification provides more than adequate written description for the methods as presently claimed. Nevertheless, for purposes of clarity and to advance prosecution, Applicants have amended claim 19 by removing language relating to immunogenic portions. In addition, claim 19 has been amended to specify that a claimed polypeptide has at least 95% identity to the entirety of SEQ ID NO: 140.

With regard to % identity language, Applicants submit that the identified T-cell immunogenicity of the polypeptide of SEQ ID NO: 140 represents a single identifying characteristic sufficient to support the relatively narrow genus of polypeptides currently claimed,

i.e., sequences having at least 95% identity to the entirety of SEQ ID NO: 140. More particularly, upon identification of SEQ ID NO: 140 as a polypeptide capable of stimulating a human T-cell response, as established by Applicants' disclosure, it would be well understood that polypeptides bearing close structural identity to SEQ ID NO: 140, as claimed, would elicit the same or similar human T-cell responses as that elicited by the polypeptide of SEQ ID NO: 140. This expectation is based upon fundamental principles of immunological recognition and cross-reactivity. To the extent that a skilled artisan would understand and appreciate that polypeptides having at least 95% identity to the entirety of SEQ ID NO: 140 can be readily made and used according to Applicants' disclosure, while achieving a substantially equivalent immune response to that achieved when using the specific polypeptide of SEQ ID NO: 140, such subject matter is submitted to have been squarely within Applicants' possession at the time the application was filed. Reconsideration of this rejection is respectfully requested.

Rejections under 35 U.S.C. §112, First Paragraph (Enablement)

Claims 19-25 stand rejected under 35 U.S.C. §112, first paragraph, because the specification allegedly does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate with the scope of the claims. The Examiner acknowledges that the instant specification is enabling for a method of stimulating an immune response using an isolated polypeptide comprising SEQ ID NO: 140. However, the Examiner alleges that the skilled artisan would need to engage in undue levels of experimentation in order to practice the methods using an immunogenic portion of SEQ ID NO: 140 or a polypeptide having at least 95% identity to SEQ ID NO: 140.

Applicants respectfully traverse this rejection and submit that the instant specification, combined with the level of skill in the art, easily enables the skilled artisan to practice the claimed methods in their full scope. Nevertheless, without acquiescence, and solely to advance prosecution, Applicants have amended claim 19 by removing language relating to immunogenic portions. In addition, claim 19 has been amended to specify that a claimed polypeptide has at least 95% identity to the entirety of SEQ ID NO: 140.

The specification as filed clearly and extensively describes illustrative techniques for preparation of a polypeptide, either expressed recombinantly or synthetically generated. These and numerous other methodologies are indeed well known and established in the art. In this respect, it is certainly not undue for a skilled artisan to understand how to make a claimed polypeptide having at least 95% identity to the entirety of SEQ ID NO: 140.

Further, upon making a polypeptide having at least 95% identity to the entirety of SEQ ID NO: 140, the skilled artisan would also have a reasonable expectation that the polypeptide would be effective for eliciting the same or similar immune response as elicited by the polypeptide of SEQ ID NO: 140. Again, this expectation is based upon the high level of structural similarity between the subject polypeptides and upon well known and fundamental principles of immunological recognition and cross-reactivity. To the extent that a skilled artisan would understand and expect that polypeptides having at least 95% identity to the entirety of SEQ ID NO: 140 could be readily made and used according to Applicants' disclosure, while achieving a substantially equivalent immune response to that achieved when using the specific polypeptide of SEQ ID NO: 140, the claimed invention is submitted to be more than sufficiently enabled by the present disclosure. Reconsideration of this rejection is respectfully requested.

Rejections under 35 U.S.C. §112, Second Paragraph

Claims 19-26 stand rejected under 35 U.S.C. §112, second paragraph, as allegedly being indefinite for failing to point out and distinctly claim the subject matter which Applicants regard as the invention. Specifically, the Examiner alleges that the recitation of "CT875 protein" is vague and appears to be "lab terminology." Further, the Examiner contends that the recitation of "a *Chlamydia* CT875 protein" is confusing because it refers to more than one CT875 protein.

Applicants respectfully traverse this rejection and submit that the presently amended claim 19 is clear and definite and would be viewed as such by the skilled individual. The term "CT875" does not represent "lab terminology," as suggested by the Examiner, but is the terminology assigned by the NCBI (the National Center for Biotechnology Information), which is a branch of National Institutes of Health. The name is descriptive for a particular locus of a transcription unit in the *Chlamydia* genome.

Nevertheless, for purposes of clarity and to advance prosecution, Applicants have amended claim 19 to recite that the immune response stimulated following administration of the claimed polypeptide is an immune response that is specific for the polypeptide of SEQ ID NO: 140. Reconsideration is respectfully requested.

Rejections under 35 U.S.C. §102(e)

Claims 19-23 stand rejected under 35 U.S.C. §102(e), as allegedly being anticipated by Probst *et al.* (U.S. Patent 6,432,916). Specifically, the Examiner asserts that Probst *et al.* discloses a method of stimulating an immune response with an immunogenic portion of the presently claimed SEQ ID NO: 140, namely SEQ ID NO: 296 of Probst *et al.*.

Applicants respectfully traverse this rejection. As noted above, for purposes of clarity and to advance prosecution, Applicants have amended claim 19 by removing language relating to immunogenic portions. In addition, claim 19 has been amended to specify that a claimed polypeptide has at least 95% identity to the entirety of SEQ ID NO: 140.

SEQ ID NO: 296 of Probst *et al.*, while bearing some relation to the presently claimed SEQ ID NO: 140, as noted by the Examiner, is not a polypeptide *having at least 95% identity to the entirety of SEQ ID NO: 140*. Accordingly, this reference does not anticipate the invention as presently claimed by Applicants. Reconsideration and withdrawal of this rejection is requested.

Rejections under 35 U.S.C. §103

Claims 19-25 stand rejected under 35 U.S.C. §103(a) as allegedly being obvious by Probst *et al.* (U.S. Patent 6,432,916), in view of Baldridge *et al.* (J. Endotoxin Research (2002) 8(6) 453-458). According to the Examiner, Probst *et al.* discloses a method of stimulating an immune response with an immunogenic portion of the presently claimed SEQ ID NO: 140 (CT875), namely SEQ ID NO: 296 in Probst *et al.* Also according to the Examiner, Baldridge *et al.* describes the administration of aminoalkyl glucosaminide 4-phosphate adjuvants, including RC-529, as recited in Applicants' claims 24 and 25. The Examiner concludes that it would have been obvious to one of ordinary skill in the art to combine the

polypeptide of Probst *et al.* with an adjuvant of Baldrige *et al.* and, in doing so, arrive at Applicants' claimed invention.

Applicants respectfully traverse. For purposes of clarity and to advance prosecution, Applicants have amended claim 19 by removing language relating to immunogenic portions. In addition, claim 19 has been amended to specify that the claimed polypeptide has at least 95% identity to the entirety of SEQ ID NO: 140.

As discussed above, SEQ ID NO: 296 of Probst *et al.* is not a polypeptide having at least 95% identity to the entirety of SEQ ID NO: 140. Further, the deficiencies of Probst *et al.* are not remedied by the disclosure of Baldrige *et al.*, since Baldrige *et al.* also fails to teach any polypeptide having at least 95% identity to the entirety of SEQ ID NO: 140. Accordingly, the cited combination of references cannot render the presently claimed invention obvious when the combination of references simply does not teach, suggest, or lead the skilled artisan to, the elements of Applicants' claims. Reconsideration and withdrawal of this rejection is requested.

The Director is authorized to charge any additional fees due by way of this Amendment, or credit any overpayment, to our Deposit Account No. 19-1090.

Favorable consideration and a Notice of Allowance are earnestly solicited.

Respectfully submitted,

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